SEP 26 2000

K000512

CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE
44 EAST INDUSTRIAL ROAD, BRANFORD, CONNECTICUT 06405
203-488-6056
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510(K) SUMMARY

Date prepared: February 11, 2000

Contact:
CAS Medical Systems, Inc.
44 E. Industrial RD.
Branford CT. 06405
(203) 488-6056
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Contact person:
Ron Jeffrey
Quality Assurance / Regulatory Affairs Manager

Device trade name: Oscillomitt

Common names: Blood Pressure Mitt

Classification

Classification Name	21 CFR Section	Product Code	Class
Blood Pressure Cuff	870.1120	74DXQ	2

Predicate Devices

CAS is claiming substantial equivalence to the following legally marketed device:

Aspect	Device	510(k) number
Blood Pressure Cuff	TuffCuff	Preamendment Device

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Device Description

Oscillomitt® is an inflatable wrap-around half mitten, encircling the Palmar Arch and leaving the fingers and thumb exposed. The device is fastened in place by a hook and loop closure. The device is comprised of a coated nylon material with a PVC inflation tube attached. It is reusable, durable and can be used on either hand of the patient. A full range of sizes is available.

Theory of Operation:

The device is used in conjunction with a standard oscillometric blood pressure monitor to non-invasively measure arterial blood pressure from the Palmar Arch of the hand. Volume oscillations in the palmer arch from arterial circulation are transmitted through the Oscillomitt® and the single supply tubing to a transducer in the oscillometric monitor.

Product Uses:

The mitt offers an alternative site for non-invasive blood pressure measurement when the traditional site (upper arm, thigh) is unavailable or contraindicated. Oscillomitt® can be used in all hospital, outpatient, physician office and emergency service care areas. Self-application makes it ideal for use in the home. The product is more comfortable than traditional arm cuffs and is ideal for the patient where traditional cuffs may not fit properly.

Intended Use

The Oscillomitt is intended for use in conjunction with CAS Oscillometric blood pressure monitors and modules to non-invasively measure arterial blood pressure from the hand of pediatric (age 2 or older) and adult patients.

Comparison of Technological Characteristics

The Oscillomitt® blood pressure mitts have essentially the same technological characteristics as the predicate devices with regard to design, materials and energy source. There are no new technological characteristics. Refer to table below:

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Predicate device is TuffCuff, a traditional blood pressures cuff for the arm or, in some cases, the leg.

Technological Characteristics	Discussion of Similarity or Difference
Operating principal	The TuffCuff can be used for ascultatory as well as oscillometric measurement. Oscillomitt is used only with oscillometric measurement.
System or stand-alone device?	Both are similar in that they comprise a system and cannot be used alone.
Manner in which it is used	Both are similar in that they intermittently restrict blood flow followed by analysis of changes in oscillation amplitude during deflation.
Ease of application	Both can be self-applied however the glove is easier.
Material	Both are made from the same materials.
Fit	TuffCuff and Oscillomitt® offer a range of sizes. NIBP can be obtained on very large people more easily with Oscillomitt due to better compliance with a large mitt and hand versus a rectangular cuff on a large conical arm.
Comfort	Oscillomitt® proves to be more comfortable.

Testing

Two studies are cited here:

1.) "Validation of the Oscillomitt® Blood Pressure Mitt using the AAMI Standard Protocol in Children". University of Tennessee – Department of Pediatrics, Memphis.

This trial was conducted using the auscultatory method as a reference for blood pressure with a traditional arm cuff vs. the Oscillomitt® and a CAS 9300 Oscillometric monitor. The subjects were 2 – 18 years of age.

Results show that the Oscillomitt gave quite an accurate representation of blood pressure with mean differences for the glove vs. the cuff of 2mmHg or less for both systolic and diastolic pressures.

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2.) "CAS study of Adult population" This study was a comparison between Oscillomitt and TuffCuff using CAS Oscillometric non-invasive blood pressure monitors

Conclusions

In accordance with 21 CFR part 807.92(b)(3) and as presented in this premarket notification, CAS Medical Systems, Inc. concludes that the new device, Oscillomitt® Blood Pressure Mitt is safe and effective and substantially equivalent to the predicate devices as described.

Other Information

CAS Medical Systems, Inc. will update this summary with additional information if requested by the FDA.

END OF SUMMARY SECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2000

CAS Medical Systems, INC.
c/o Mr. Ron Jeffrey
QA/RA Manager
44 East Industrial Road
Branford, CT 06405

Re: K000512
Trade Name: Oscillomitt®, Models CM1050, CM 1040, CM 1030, and CM 1020
Regulatory Class: II (two)
Product Code: DXQ
Dated: June 5, 2000
Received: June 9, 2000

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OSCILLOMITT®

STATEMENT OF INDICATIONS FOR USE

The Oscillomitt is intended for use in conjunction with CAS Oscillometric blood pressure monitors and modules to non-invasively measure arterial blood pressure from the hand of pediatric (age 2 or older) and adult patients.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000512